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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,662	05/24/2007	Ari M. Melnick	96700/1146	6667

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EXAMINER	
AUDET, MAURY A	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
12/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,662	MELNICK ET AL.	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-12,17,20,26,48,50,51,53-57,61 and 62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *61* is/are objected to.

8)☒ Claim(s) *1,7-12,17,20,26,48,50,51,53-57,61 and 62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/12/06* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1, 7-12, 17, 20, 26, drawn to an compound/peptide comprising the 17mer genus amino acid sequence SEQ ID NO: 10 (e.g. distinct species thereof being SEQ ID NOS: 1-3).

II. Claims 48, 50-51, 53-56, drawn to a method of treating a cancer that requires BCL6 repression, using a compound/peptide comprising the 17mer genus amino acid sequence SEQ ID NO: 10 (e.g. distinct species thereof being SEQ ID NOS: 1-3).

III. Claim 57, drawn to the distinct 127mer artificial/synthetic peptide of SEQ ID NO: 12.

IV. Claim 61, drawn to a vector comprising A polynucleotide capable of expressing the 127mer peptide of SEQ ID NO: 12.

[NOTE: See claim objection below, claim 60 to polynucleotide has been cancelled].

V. Claim 62, drawn to a method of determining whether a test compound inhibits corepressor binding to BCL6, the method comprising determining whether the test compound binds to a BCL6 lateral groove, wherein a compound that binds to a BGL6 lateral groove inhibits corepressor binding to BCL6 [using SEQ ID NOS: 1-3??].

Lack of Unity

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and a process specially adapted for the manufacture of said product; or (2) a product and a process of use of said product; or (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) a process and an apparatus or means specifically designed for carrying out the said process; or (5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

No 'Special' Technical Feature or Markush Group

The 'technical feature' running through the claims is assumed to be a peptide. Namely, any of SEQ ID NOS: 10 (genus) to SEQ ID NOS: 1-3 (claim 1), or independently claimed SEQ ID NO: 12 (claim 57). As noted below, the art teaches 1 or more of these products:

> Morris et al. [US 2002/0182586 A1, claim 5, entire document] generally teaches peptides comprising one or more of SEQ ID NO: 1-3, and/or 10 (see i.e. claim 5, entire document); however, the reference made no reference to use in BCL6 functionally binding compounds or methods of using the same where BCL6 is bound" (see Form 237, Reasoned Statement).

The disposition finds:

1. The technical feature is known, and does not constitute a 'special' technical feature.

2. Furthermore, since each peptide is a distinct peptide, and SEQ ID NO: 12 (127mer) bears no overlap with even the 17mer genus peptide of SEQ ID NO: 10 (which includes structurally distinct 17mer species SEQ ID NOS: 1-3), none of which can be said to be 'special' technical feature, because none of the distinct peptides runs through each and every claim/group. For the members of a Markush group to have unity of invention, *all* members must have a common core structure or be a member of an art recognized class. Neither of the above applies to the peptides of the present invention. Thus, the Markush groups, and hence Inventions drawn thereto, lack unity of invention. (See Annex B to PCT Administrative Instructions, P. A1-59). **Therefore, under either ground (known peptide(s) or Markush group without common core structure or a member of an art recognized class), no 'special' technical feature is present and the claims lack unity of invention.**

Requirement for Election of a Single Distinct Peptide as the Invention

As described above, SEQ ID NO: 10 is drawn to a genus peptide formula, containing distinct species peptides therein, e.g. SEQ ID NOS: 1-3. Any one of which would require an individual sequence and/or structure search of each such variation of any amino acid, as there is no overlapping coextensive search possible. The search of each and every peptide would thus constitute an undue search burden; as art on one would not read on another, absent express evidence to the contrary by Applicant's admission. **Therefore, if one of the 3 Groups of I-II and V is elected as the invention, Applicant must elect a single peptide** (e.g. SEQ ID NO: 1), as the invention (not species), to which the elected Invention group will be searched.

This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In re Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Objections

Claim 61 is objected to under 37 CFR 1.75(c), as being of improper dependent form for depending to a cancelled claim 60, formerly to the polynucleotide. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Observations/Revised Disposition of Written Opinion (Form 237)

The present application is a 371 National Stage of PCT/US04/42418, in which this Examiner conducted both the International Search Report and Written Report (Forms 210 and 237). A similar claimset therein was deemed to contain novelty and inventive step; which is maintained (pending updated searech) as to an independently claimed 127mer artificial/synthetic peptide of SEQ ID NO: 12. Additionally, the same was held as to a first independent claim drawn to a product of peptide amino acid SEQ ID NO: 10 (genus; species SEQ ID NOS: 1-3 thereof) combined with **functional language** where said peptide is capable of binding the BCL6 lateral groove to prevent/reduce binding of a corepressor to the lateral groove). **However, upon reconsideration, the Examiner believes in hindsight he mistakenly (until further reviewed) granted these functional limitations patentable weight as to the product; namely the one or more known peptides of the genus SEQ ID NO: 10 – as noted as being taught by:**

> "Morris et al. [US 2002/0182586 A1, claim 5, entire document] generally teaches peptides comprising one or more of SEQ ID NO: 1-3, and/or 10 (see i.e. claim 5, entire document); however, the reference made no reference to use in BCL6 functionally

binding compounds or methods of using the same where BCL6 is bound" (see Form 237, Reasoned Statement).

Should Group I above be elected as the invention, Morris et al. would be applied as art, where applicable over any of SEQ ID NOS: 10 (genus) or 1-3; as teaching the product, even if not the functional language/use, thereof. It is noted that Morris et al. was not indicated as teaching independently claimed 127mer artificial/synthetic peptide of SEQ ID NO: 12.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 12/16/2009
/Maury Audet/
Examiner, Art Unit 1654
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